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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,118	11/13/2003	Toshiyuki Takai	671302-2002	8301

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,118	TAKAI ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of December 30, 2005 on March 27, 2006. Claims 1-5 are amended. Claims 6-18 are cancelled. Claims 19 and 20 are new.

Claims 1-5, 19, 20 are under consideration.

It is noted that Applicant has requested an interview should the instant application not be in condition for allowance (Applicant's response, page 9). However, given the time constraints upon the Examiner to respond to applicant's amendment, an interview was not possible. If Applicant wishes to discuss this Application with the Examiner and SPE or Primary, Applicant may contact the Examiner at the number provided at the end of this Action to set up an interview.

Withdrawn Rejections

35 U.S.C. § 101

Applicant's arguments, see page 3 of Applicant's response, filed March 27, 2006, with respect to the rejection of claims 1-5 have been fully considered and are persuasive. Applicant has amended the claims to exclude mice comprising a natural mutation in chromosomal DAP12, which is nonstatutory matter. The rejection of claims 1-5 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 19, 20 remain rejected in modified form under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a transgenic mouse comprising a homozygous disruption of DAP12 (DNAX Activation Protein 12) in its genome, wherein the transgenic mouse exhibits hypomyelinosis of the thalamus,

does not reasonably provide enablement for

a transgenic mouse model of oligodendrocyte developmental disorders wherein the transgenic mouse comprises a disruption in chromosomal DAP12 (DNAX Activation Protein 12) gene function, and wherein the transgenic mouse exhibits hypomyelinosis of the thalamus.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record December 30, 2005.

Response to Arguments

Applicant's arguments filed March 27, 2006, have been fully considered but they are only persuasive in part.

Regarding the issue that the Examiner had indicated that the specification and art provided guidance on making a transgenic mouse comprising a disruption in its

endogenous DAP12 gene, but does not provide sufficient guidance on how to make other non-human animals, Applicant has amended the claims to "transgenic mouse." The rejection of the claims with regard to this issue is withdrawn.

However, the rejections are maintained as follows.

While Applicant has amended claim 1 to include the phrase, "hypomyelinosis of the thalamus" to indicate the phenotype exhibited by the claimed mice, the preamble of claim 1 is drawn to, "a transgenic mouse model of oligodendrocyte developmental disorders." As indicated on page 7-8 of the Office Action, December 30, 2005, oligodendrocyte developmental disorders encompasses a wide variety of different disorders. While the specification teaches one kind of oligodendrocyte developmental disorder, i.e. hypomyelinosis of the thalamus, the specification does not teach other kinds of oligodendrocyte developmental disorders such that the claim is enabled for its full breadth. As such, the rejection regarding this issue remains.

Applicant indicates that there is support for Huntington's disease as a phenotype exhibited by the claimed mice as Geyer et al. teaches that humans with Huntington's disease can lead to abnormal sensorimotor gating and that one of the phenotypes exhibited by the claimed mice is abnormal sensorimotor gating (Applicant's response, page 4). In response, the argument is not persuasive because the etiology and pathology of Huntington's disease does not depend on DAP12. While Nasu-Hakola disease patients and the claimed mice exhibit abnormal sensorimotor gating, the abnormal sensorimotor gating depends on DAP12 and not on the etiology and pathology of Huntington's disease. While there is a shared phenotype of abnormal

sensorimotor gating between Huntington's disease and Nasu-Hakola disease, the genes involved in this phenotype could be different between the two diseases. This possibility stands as nothing in the art or the specification indicates a relationship between DAP12 and Huntington's disease. As such, the rejection regarding this issue remains.

It is noted that the Office Action, December 30, 2005, had indicated that only homozygous DAP12 disrupted mice were enabled (Office Action, page 5, opening sentence). While the Office Action did not expound on the fact that the only mice that exhibited the phenotype was the homozygous mice and not heterozygous mice, no response was provided by the Applicant that there was enablement for heterozygous mice. It is noted that the claims encompass heterozygous mice, wherein the heterozygous mice exhibit a phenotype. However, nothing in the specification provides this support. As such, the rejection regarding this issue remains.

For the reasons described above, the claims remain rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 19, 20 remain rejected under 35 U.S.C. 102(a) as being anticipated by Bakker et al., 2000, Immunity, 13: 345-353 for reasons of record, December 30, 2005.

Claims 1, 3-5, 19, 20 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tomasello et al., 2000, Immunity, 13: 355-364, for reasons of record, December 30, 2005.

Claims 1, 3-5, 19, 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Vivier et al., U.S. Patent Application, publication number US 2004/0045041, published March 4, 2004, priority date September 20, 2000, for reasons of record December 30, 2005.

Response to Arguments

Applicant's arguments filed March 27, 2005 have been fully considered but they are not persuasive.

Applicant indicates that MPEP 2131 states in part that, "(a) claim is anticipated only if **each and every element** set for in the claims is found, **either expressly or inherently** described, in a single prior art reference." Further, for a proper anticipation rejection the reference "must **clearly and unequivocally disclose** the claimed compound...(Applicant's emphasis, Applicant's response, page 5)." In response, claim 1 (and its dependent claims) is drawn to a transgenic mouse comprising a disruption in chromosomal DAP12. Bakker et al., Tomasello et al., and Vivier et al. teach mice

whose genome fits this limitation. Regarding the issue that the mice taught by Bakker et al., Tomasello et al., and Vivier et al. do not exhibit Nasu-Hakola disease, the Examiner determined that the mice taught by Bakker et al., Tomasello et al., and Vivier et al. fit the structural limitation of the claims and therefore would inherently exhibit the same phenotypes as the claimed mice.

Applicant indicates that Bakker et al., Tomasello et al., and Vivier et al. do not at any point teach or suggest or disclose any effects on brain tissue, including the presence or absence of hypomyelinosis of the thalamus (Applicant's response, page 7, 1st and 2nd parag.). In response, Bakker et al., Tomasello et al., and Vivier et al. do suggest that mice that they disclose will be studied as a model for Nasu-Hakola disease (Office Action, page 10, 3rd parag., page 12, 2nd parag., page 13, 3rd parag.). As such, Bakker et al., Tomasello et al., and Vivier et al. provide additional guidance that the mice are would likely be models of Nasu-Hakola disease. As such, Applicant has not provided evidence to the contrary, that while the mice taught by Bakker et al., Tomasello et al., and Vivier et al., structurally meet the limitations of the claims, that the mice do not in fact exhibit hypomyelinosis of the thalamus.

The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ

1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

As such, the rejection remains.

Applicant indicates that Bakker et al., Tomasello et al., and Vivier et al., are different from the specific mutations of the instant invention. Applicant indicates that that it is well known in the field of recombinant genetics, that different mutations in the same gene can result in different phenotypes. As such, it is **entirely unknown** as to whether the prior described mice would exhibit the required phenotype (Applicant's emphasis, Applicant's response, page 7, 3rd parag.). In response, if what Applicant asserts is true, then the claims do not reflect that a specific mutation in DAP12 results hypomyelinosis of the thalamus. Rather, claim 1 (and its dependent claims 3-5, 19, 20) read on any disruption of DAP12. This is contrary to what Applicant asserts as true.

As such, the rejections as they apply to the instant invention remains.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER